

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Remacle, et al.
Appl. No. : 10/035,822
Filed : December 27, 2001
For : DETECTION AND/OR
QUANTIFICATION OF A TARGET
MOLECULE BY BINDING WITH A
CAPTURE MOLECULE FIXED ON
THE SURFACE OF A DISC
Examiner : Sisson, Bradley L.
Group Art Unit: 1634

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

1. This Declaration is being submitted to demonstrate that, after reading the specification of the subject patent application, an individual having ordinary skill in the field of CDs and DVDs and devices for reading CDs and DVDs would recognize that the inventors possessed the CDs or DVDs comprising one or more nucleic acid capture molecules bound to a first specific area of the disc that does not comprise tracks or grooves with registered data and comprising registered data in the form of lands and pits that can be read by a CD or DVD reading device in a second specific area of the disc which are claimed in the above-identified application. In addition, this Declaration is being submitted to demonstrate that, after reading the specification of the subject patent application, a person with an ordinary skill in the art would have been able to follow the directions in the Specification to make and use the foregoing CDs or DVDs.



2. This Declaration is also being submitted to demonstrate that, after reading the specification of the subject patent application, an individual having ordinary skill in the field of CDs and DVDs and devices for reading CDs and DVDs would recognize that the inventors possessed the detection and/or reading devices comprising a first reading device for reading the registered data and a second reading device for reading the signal resulting from the binding between a target molecule and a nucleic acid capture molecule on the surface of a CD or DVD which are claimed in the above-identified application. In addition, this Declaration is being submitted to demonstrate that a person with an ordinary skill in the art would have been able to follow the directions in the Specification to make and use the foregoing detection and/or reading devices.

3. I am not an inventor on the above-identified patent application and I am familiar with the specification and the claims at issue.

4. Prior to December 30, 1997, the date to which the above-identified application claims priority, I had extensive experience in the field of compact discs and compact disc readers as indicated in the attached Curriculum Vitae provided as Exhibit A of the Declaration.

5. I am not affiliated with Eppendorf Array Technologies (the assignee of the above-identified application), although in the past the company I am the director (WOW) provided Eppendorf Array Technologies with a CD arrayer for spotting nucleic acids on CDs claimed in the present application. I will not financially benefit from the issuance of the above-identified application as a U.S. patent. I was, however, paid a wage of \$250/hour for my expert services. In particular, this wage was paid to compensate me for the time I spent reading the specification and claims of the subject patent application, and formulating the opinion expressed herein. Payment of this wage was not contingent on any particular outcome.

6. After reading the subject patent application, I understood that the inventors possessed CDs or DVDs comprising binary information that is to be read at the same time that the binding of a target nucleic acid molecule to a capture nucleic acid molecule bound to the disc is being detected. In particular, the recording of binary information on a desired surface of the CD or DVD is described in the specification at page 4, line 14 through page 15, line 15, page 9, line 27 through page 11, line 8, page 20, lines 5-13, and page 40, lines 11-28. In summary, the binary data is recorded using a laser based engraving machine and is present on

a CD or DVD as pits and lands in a continuous spiral track as described in "The complete recordable-CD guide" cited in the Specification. The transition between the pits and the lands measured as a phase shift in the reflected laser beam is indicated as binary 1. The specific sequences of 0's and 1's correspond to data bytes which are converted into information (words, numbers, sounds, images, etc.). For example, the information may relate to the location and identification of the capture molecules bound to the CD or DVD surface at locations devoid of the track(s) with binary information.

This methodology for recording binary data on the desired surface area of the CDs or DVDs is the same methodology conventionally used to record binary data, such as words, numbers, sounds, images etc., on a CD or DVD. Such methodology was conventional as of December 30, 1997 (the date U.S. Provisional Patent Application No. 60/071,726, to which the present application claims priority was filed). Accordingly, after reading the specification, I understood that the inventors possessed methods for recording binary data on a desired surface area of a CD or DVD and I could readily make and use such CDs or DVDs based on the description in the specification.

7. The specification describes methodology for attaching nucleic acid capture molecules to a CD or DVD on a surface that does not comprise tracks or grooves with registered data at page 7, lines 7-9, page 13, line 24 through page 14, line 15, page 19, lines 21-25, page 20, lines 14-16, and figures 4-8, and 11-13. The Specification is very clear in specifying that the attachment of the arrays of nucleic acids does not impact the binary data recorded on other areas of the disc. For example, the Specification teaches that the areas of the disc dedicated to the assays may be located on the side of the disc opposite of the binary data side. Alternatively, the array parts of the CD may be located on the same side of the surface of the disc or inside the disc such that they do not interfere with the spiral tracks containing binary information (page 13, line 24 through page 14, line 8, page 21, lines 14-16).

8. The specification describes methods for chemically linking nucleic acid capture molecules to the surface of the disc at locations which do not contain registered data. Such chemical procedures are described, for example, at 20, line 22-page 21, line 12. Methods for coating the discs with materials which facilitate the attachment of the capture molecules are described at, for example, page 11, lines 18-33 and page 45, line 1-page 46, line 14. Methods for applying coatings, such as those utilized to attach the nucleic acid capture molecules, to

CDs or DVDs were well known in the art as of December 1997. In addition, Examples 1, 2, and 7 provide actual examples of the manufacturing of discs having nucleic acid capture molecules attached thereto.

Accordingly, after reading the specification, I understood that the inventors possessed methods for attaching nucleic acid capture molecules to a first surface area of the CD or DVD which does not comprise tracks or grooves with registered data and which contains binary data on a second surface area and I could make and use such CDs or DVDs based on the description in the specification.

9. The specification describes the CD/DVD as comprising a "disc platform" having at least partially a circular shape for accommodating the spiral track for CD/DVD binary data, but makes it clear that the overall shape of the CD/DVD is not limited to just a circle (see page 6, lines 17-30 and page 13, lines 13-18). As of December 1997, CDs or DVDs could be manufactured in any external shape: circular, square, rectangular, elliptic, hexagonal, octagonal, triangle, etc., as long as the internal part of its surface accommodated spiral tracks for binary information. Accordingly, after reading the specification, I understood that the inventors possessed the claimed CD/DVDs of any external shape or size having binary data recorded in one area of the surface of the disc and having nucleic acid capture molecules located in a second area which does not comprise tracks or grooves with binary data and I could make and use such CDs or DVDs based on the description in the Specification.

10. The Specification also teaches a disc reading device for reading of the above-described CD/DVDs. Based on this description, it is apparent to me that the reader has a standard platform, such as those conventionally used in commercial CD/DVD readers for reading the binary information provided on the internal circle of the claimed disc in a spiral track. This standard platform is supplemented with an additional reading device for the detection of the signals from the binding of target nucleic acids to the capture nucleic acids located on a second portion of the disc. Figures 11, 12, 13 and 14 provide electronic schematics for both of the detectors, while the Specification on pages 37-41 goes into specific details about the way the claimed disc reader is built. In each of the 4 versions of the disc reader described, a first illuminating and detection device is the normal CD or DVD reader which allows the reading of binary information off the claimed CD or DVD. Such technology has been known in the art as standard as evidenced by textbooks in their second

editions as of December 1997 (listed in the Specification on pages 15-16). The design of the second illuminating and reading device for detecting the signals from the portion the disc comprising the nucleic acid capture molecules depends on the type of the signal to be detected as well as on the location of the capture molecules on the disc (on the same surface or on the opposite surface from the binary data). The illuminating part of the second reader may be the same one used for the binary portion of the information on the claimed disc (laser) or may be a separate light source (laser, fluorescent, or visible light). In particular, the illuminating part of the second reader is a light beam which moves along one dimension so as to cover the radius of the disc. Light sources of each of these types were conventional and readily available as of December 30, 1997 (the date U.S. Provisional Patent Application No. 60/071,726, to which the present application claims priority was filed). Motors for moving the light beam along one dimension so as to cover the radius of the disc were also conventional and readily available as of December 30, 1997. Similarly, detectors for detecting a signal resulting from the binding between a target nucleic acid and a capture nucleic acid were conventional and readily available as of December 30, 1997. In particular, such detector could be a photodiode. The detecting part of the second reader can be easily constructed based on the electronic schematics in figures 11-14. Accordingly, after reading the specification, I understood that the inventors possessed an apparatus comprising a first reading device for reading registered data by penetration and reflection of a laser beam from the lands and pits in a specific surface area of the claimed CDs or DVDs and a second reading device for reading the signal resulting from the binding between a target nucleic acid and a capture nucleic acid in a specific surface area of the claimed CDs or DVDs, wherein the second reading devices is an optical system for the detection of a light beam which moves along one dimension so as to cover the radius of the disc. In addition, I could make and use such devices based on the description in the specification.

11. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or patent issuing therefrom.

Appl. No. : 10/035,822
Filed : December 27, 2001

Dated: 19th February 2007

By: 

Joel Demarteau

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EXHIBIT A

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joel.demartea@wowcompany.com
married, two children
born on the 10th of May 1946

Education & Qualifications

- *Bachelor in Physics*
- *Bachelor in Philosophy*
- *Master in Informatics*

Additional Qualifications

- *4 weeks at CRC in Paris (1988 - 89) (management)*
- *3,5 weeks Euroleader Edimbourg + Belgium (1995) (business figures)*
- *PME Plus Ichech formation for PME director (1996-2001)*
- *Plato (2 years monthly cours) tools for PME progress*
- *Lambda plus (administrator group)*
- *APM International Association for Progress in Management*
- *GRD (R&D group Industry/University)*

Professional Experience

- *3 years assistant and professor at the University Notre-Dame de la Paix Namur (FUNDP)*
- *5 years informatics director + PME (80 persons)*
- *9 years founder and director of Unina PME (1 to 100 persons)*
- *16 years founder and director of Wow PME (1 to 45 persons)*
- *7 years co-administrator of WIN (7 persons)*
- *5 years co-director of ACTE (6 persons)*
- *3 years co-director of Biosentech (Biosensors)*
- *inventor and assignee of different patents*

Competences acquired at Wow

- **computers:** software realization, modification and validation, hardware and software integration, industrial vision,...
- **data processing:** acquisition, regulation, telecommunication, data security,...
- **electronics:** low and high power development, realization and integration, mass-production,...
- **mechanics:** mechanical engineering, robotics, CAD, CAM, CNC,...
- **physics:** resonance, wave patterns,...
- **mathematics:** modelling, simulation,...
- **composite materials:** fiberglass, polyester, polyurethane (PU RIM), design and realization of moulds,...
- **maintenance:** robotics, production line, hydraulics,...